Claim 1 has been amended to include the functional recitation that the recited nucleic acid molecule encodes a polypeptide that exhibits lipase activity. This recitation is disclosed in the specification, for example at page 76, lines 17-30.

In claims 1, 2, 29-32, and 35-37, the phrase "amino acid sequence encoded by SEQ ID NO: 45 or 46" has been modified in each instance by deleting "45 or". Each of SEQ ID NOs: 45 and 46 encode the same amino acid sequence, so this amendment merely removes redundancy.

Claims 30 and 31 were amended to recite what was already inherently recited therein (i.e., that the recited nucleic acid encodes a <u>polypeptide</u> comprising the recited amino acid residues).

Claim 33 was amended to recite that the encoded amino acid residues comprise an immunogenic portion of the protein encoded by SEQ ID NO: 46. This claim is supported in the specification, for example at the paragraph bridging pages 82 and 83 of the specification. New claims 41 and 42 are similarly supported.

Claims 38 and 40 (which recite that the encoded polypeptide exhibits lipase activity) were redundant in view of the amendment of claim 1, and have been amended to depend indirectly from new independent claim 43 (which recites that the encoded polypeptide comprises an immunogenic portion of the protein encoded by SEQ ID NO: 46).

New independent claim 43 is identical to claim 1, except that it recites that the nucleic acid molecule encodes an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO: 46 (i.e., rather than that it encodes a polypeptide that exhibits lipase activity, as in claim 1). This recitation is supported in the specification, for example at the paragraph bridging pages 82 and 83 of the specification.

New dependent claims 44-65 substantially mirror the recitations of dependent claims 39, 24-31, 33, 32, 2-6, 34, 7, 12, and 35-37, respectively, with the following exceptions. New claim 53 recites that the encoded polypeptide exhibits lipase activity (whereas mirrored claim 33 recites that it includes an immunogenic portion). New claim 62 is a method of producing an immunogenic portion (whereas mirrored claim 12 is a method of producing a polypeptide that exhibits lipase activity). The recitations of claims 53 and 62 are also supported in the specification at the paragraph bridging pages 82 and 83 of the specification.

New independent claim 66 is supported in the specification, for example at the paragraph bridging pages 73 and 74.

For the foregoing reasons, the Applicants respectfully contend that the amendments and additions made herein do not include new matter.

Overview of this Amendment

The Applicants believe that agreement was reached during the 15 October 2002 interview that the application includes allowable subject matter, relating to three areas. These areas are:

- I) Nucleic acid molecules that encode a polypeptide which exhibits lipase activity. Claims 1-7, 12, 24-37, 39, 41, and 42 relate to this subject matter. Claim 1 is the only independent claim in this group.
- II) <u>Nucleic acid molecules that encode an immunogenic portion of the protein encoded by SEQ ID NO: 46</u>. Claims 38, 40, and 43-65 relate to this subject matter. Claim 43 is the only independent claim in this group.
- III) Nucleic acid molecules that include a significant region of sequence identity with SEQ ID NO: 45 or 46 and are useful as probes or primers. Independent claim 66 relates to this subject matter.

Although the Applicants believe that additional subject matter is allowable (e.g., relating to a broader range of probe, primer, and antisense polynucleotides), the Examiners indicated during the interview that they were not inclined to allow claims directed to additional subject matter at that time. Accordingly, the Applicants have canceled claims directed to the additional subject matter without prejudice, in order to advance prosecution of this application to allowance as expeditiously as possible.

The Applicants have the following responses to the issues raised by the Examiner in the Office Action dated 20 May 2002.

References Cited on Form PTO-1449

The Examiner has not returned initialed copies of the two PTO-1449 forms to indicate that the references cited on those forms have been considered. The Applicants provided a copy of each Form PTO-1449 that has been filed during the prosecution of this application, as well as copies of the references cited on those forms with the response to the previous Office Action which was mailed on 14 January 2002 (Paper No. 8). During the 15 October 2002 interview, the Examiner suggested that another copy of the cited references should be forwarded **by hand delivery** to her for consideration. The Applicants forwarded a copy of each of these references to the Examiner for her consideration by hand delivery on 20 November 2002. Consideration of the references and return of initialed forms PTO-1449 are requested.

Claims 38 and 40

The Examiner previously objected that claims 38 and 40 were substantially identical. Claims 38 and 40 have been amended to depend from separate claims, and the Examiner's objection is believed to be moot.

Rejections Pursuant to 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1, 3-7, 12, 24-28, 30-34, and 36-40 pursuant to the first paragraph of 35 U.S.C. § 112. In the Examiner's view, the claims are not enabled because the claims include within their scope molecules that do not exhibit lipase activity or some other appropriate functionality.

Each of the rejected claims presently recites (or depends from a claim that recites) that the encoded polypeptide exhibits lipase activity. The Examiner's rejection is believed to be most for this reason.

The Examiner's rejection is also believed to be inapplicable to the other pending claims. Each pending claim recites that the nucleic acid molecule i) encodes a polypeptide that exhibits lipase activity, ii) encodes an immunogenic portion of the protein encoded by SEQ ID NO: 46, or iii) is a probe or primer that has a nucleotide sequence identical to at least 100 consecutive residues of SEQ ID NO: 45 or 46 or its complement. Because the Examiners

indicated that all three of these recitations limited the claimed subject matter to that which the Examiners consider allowable, all of the pending claims are believed to be sufficiently enabled and in condition for allowance.

During the 19 and 20 November 2002 telephone calls, the Examiner raised an issue regarding how claims relating to, for example, both i) an isolated nucleic acid molecule that encodes a polypeptide which exhibits lipase activity and ii) the complement of that molecule should be worded. The Applicants have amended the claims so that they recite, following this example, the isolated nucleic acid molecule "or its complement." The Applicants believe that this wording makes it clear that they are not asserting that the non-coding strand encodes a polypeptide having the same functionality as the coding strand. The Applicants also believe that this is the same meaning that the claims originally would have to the skilled artisan, and that this amendment does not serve to narrow the scope of the claims.

During the 19 and 20 November 2002 telephone calls, the Examiner also raised an issue regarding whether reciting a minimum size for a polynucleotide or a polypeptide creates doubt regarding whether molecules having the minimum size would exhibit the functional properties recited in the claims. The Applicants have, as the Examiner suggested, removed the recitations of minimum size from several of the claims, including the independent claims. However, the Applicants believe that recitation of a minimum size is not an assertion that any or all molecules having that minimum size will exhibit the functionality recited elsewhere in the claims. For this reason, the Applicants do not believe that deletion of the minimum size recitations from the claims narrows the claims in any way, nor that this deletion was necessary for patentability. The Examiner is requested to review dependent claims 27, 28, 31, 48, 49, and 52 (in which minimum size recitations have been retained) and confirm that deletion of the recitations in those claims is not required.

Summary

The Applicants respectfully contend that each of claims 1-7, 12, and 24-66 is in condition for allowance. Reconsideration and allowance of all of these claims are respectfully requested at the earliest possible time.

Respectfully submitted,

SEAN AT McCARTHY ET AL.

(Date)

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Enclosures: Petition for Extension of Time

Marked-Up Copy of Claims Amended Clean Copy of Claims, as Amended



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Marked-Up Copy of Claims Amended in the Amendment and Request for Reconsideration Filed Together with the Request for Continued Examination Filed on 20 November 2002

- 1. (Thrice Amended) An isolated nucleic acid molecule, or its complement, wherein the isolated nucleic acid i) encodes a polypeptide which exhibits lipase activity and ii) is selected from the group consisting of:
- a) a nucleic acid molecule having a nucleotide sequence which is at least 90% identical to the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof;
- b) a nucleic acid molecule comprising at least 100 nucleotide residues and having a nucleotide sequence identical to at least 100 consecutive nucleotide residues a fragment of SEQ ID NO: 45 or 46, or a complement thereof;
- c) a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: 45 or 46;
- d) a nucleic acid molecule which encodes at least 20 consecutive amino acid residues a fragment of the amino acid sequence encoded by SEQ ID NO: 45 or 46; and
- e) a nucleic acid molecule which encodes a variant of the amino acid sequence encoded by SEQ ID NO: 45 or 46, wherein the nucleic acid molecule hybridizes in 6× sodium chloride/sodium citrate (SSC) at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46-or a complement thereof.

- 2. (Twice Amended) The isolated nucleic acid molecule of claim 1, which or its complement, wherein the molecule is selected from the group consisting of:
- a) a nucleic acid having the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof; and
- b) a nucleic acid molecule which encodes the amino acid sequence encoded by SEQ ID NO: 45 or 46.
- 3. (Amended) The nucleic acid molecule of claim 1, or its complement, further comprising vector nucleic acid sequences.
- 4. (Amended) The nucleic acid molecule of claim 1, or its complement, further comprising nucleic acid sequences encoding a heterologous polypeptide.
- 5. (Amended) A host cell which contains the nucleic acid molecule of claim 1 or its complement.
- 7. (Amended) A non-human mammalian host cell containing the nucleic acid molecule of claim 1 or its complement.
- 12. (Thrice Amended) A method for producing a polypeptide selected from the group consisting of:
 - a) a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: 45 or 46;
 - b) a polypeptide comprising at least 20 contiguous amino acids of the amino acid sequence encoded by SEQ ID NO: 45 or 46; and

Attorney Docket No. 10147-6 (MBI099-030)

U.S. Application Serial No. 09/333,159

e) a variant of a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: 45 or 46, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes in 6× SSC at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof;

that exhibits lipase activity, the method comprising culturing the host cell of claim 5 under conditions in which the nucleic acid molecule is expressed.

- 24. (Amended) The isolated nucleic acid molecule of claim 1, or its complement, wherein the nucleic acid molecule has a sequence which is at least 90% identical to the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof.
- 25. (Amended) The isolated nucleic acid molecule of claim 24, or its complement, wherein the nucleic acid molecule has a sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof.
- 26. (Amended) The isolated nucleic acid molecule of claim 1, or its complement, wherein the nucleic acid molecule comprises at least 100 nucleotide residues and has a nucleotide sequence identical to at least 100 consecutive nucleotide residues a fragment of SEQ ID NO: 45 or 46, or a complement thereof.
- 27. (Amended) The isolated nucleic acid molecule of claim 26, or its complement, wherein the nucleic acid molecule comprises at least 150 nucleotide residues and has a nucleotide sequence identical to at least 150 consecutive nucleotide residues of SEQ ID NO: 45 or 46, or a complement thereof.
- 28. (Amended) The isolated nucleic acid molecule of claim 27, or its complement, wherein the nucleic acid molecule comprises at least 500 nucleotide residues and

Attorney Docket No. 10147-6 (MBI099-030)

U.S. Application Serial No. 09/333,159

has a nucleotide sequence identical to at least 500 consecutive nucleotide residues of SEQ ID NO: 45 or 46, or a complement thereof.

- 29. (Amended) The isolated nucleic acid molecule of claim 1, or its complement, wherein the nucleic acid molecule encodes a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: 45 or 46.
- 30. (Twice Amended) The isolated nucleic acid molecule of claim 1, or its complement, wherein the nucleic acid molecule encodes a polypeptide comprising a fragment at least 20 consecutive amino acid residues of the amino acid sequence encoded by SEQ ID NO: 45 or 46.
- 31. (Amended) The isolated nucleic acid molecule of claim 30, or its complement, wherein the nucleic acid molecule encodes a polypeptide comprising at least 25 consecutive amino acid residues of the amino acid sequence encoded by SEQ ID NO: 45 or 46.
- 32. (Twice Amended) The isolated nucleic acid molecule of claim 1, or its complement, wherein the nucleic acid molecule encodes a variant of the amino acid sequence encoded by SEQ ID NO: 45-or 46, wherein the nucleic acid molecule hybridizes in 6× SSC at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46-or a complement thereof.
- 33. (Amended) The isolated nucleic acid molecule of claim 30, or its complement, wherein the polypeptide exhibits lipase activity consecutive amino acid residues comprise an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO: 46.

Attorney Docket No. 10147-6 (MBI099-030)

U.S. Application Serial No. 09/333,159

- 35. (Amended) The method of claim 12, wherein the polypeptide comprises the amino acid sequence encoded by SEQ ID NO: 45 or 46.
- 36. (Amended) The method of claim 12, wherein the polypeptide comprises at least 18 contiguous amino acids a fragment of the amino acid sequence encoded by SEQ ID NO: 45 or 46.
- 37. (Twice Amended) The method of claim 12, wherein the polypeptide is a variant of the polypeptide encoded by SEQ ID NO: 45 or 46, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes in 6× SSC at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof.
- 38. (Amended) The method of claim-12 64, wherein the polypeptide exhibits lipase activity.
- 39. (Amended) The isolated nucleic acid molecule of claim 1, or its complement, wherein the molecule hybridizes in 6× SSC at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46-or a complement thereof.
- 40. (Amended) The method of claim-12.65, wherein the polypeptide exhibits lipase activity.